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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/549,409 | 09/14/2005 | Roque Humberto Ferreyro | 101896-0890 | 1699 |

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NUTTER MCCLENNEN & FISH LLP
SEAPORT WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

| EXAMINER | |
|---|---|
| BOLES, SAMEH RAAFAT | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3775 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 06/25/2010 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/549,409 | FERREYRO ET AL. | |
| | Examiner | Art Unit | |
| | SAMEH BOLES | 3775 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *8,12,20,36-39,50,51,59-61 and 78* is/are pending in the application.

4a) Of the above claim(s) *60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,12,20,36-39,50,51,59,61 and 78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/10/10,4/1/10,3/5/10,2/25/10, 6/11/09,9/5/08,7/21/08,3/23/06.

## DETAILED ACTION

According to the Amendment filed on June 11, 2009, claims 1-7, 9-11, 13-19, 21-35, 40-49, 52-58, 62-77 have been cancelled, claim 60 has been withdrawn, claims 8, 12, 20, 36, 59 have been amended and claims 8, 12, 20, 36-39, 50-51, 59, 61, 78 have been examined in this office action.

### *Specification*

1. Claims 19 and 36 were previously objected. Applicant cancelled claim 19 and amended claim 36. therefore the rejection is moot

### *Claim Rejections - 35 USC § 112*

2. Claims 8-17, 19, 38, 40, 59, 61, 62 were previously rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant cancelled claims 7, 9-11, 13-17, 19, 40 and 62; also, applicant amended claims 8, 12, 20, 38, 59 to conform to the specification; Regarding claim 61, applicant took no action, because it appears to be supported in paragraph 57 of the specification, therefore the rejection of claims 8-17, 19, 38, 40, 59, 61, 62 is moot.

3. Claims 10, 11, 12, 15, 16, 19 were previously rejected under U.S.C. 112, second paragraph because there is insufficient antecedent basis for this limitation in the claims.

Applicant has cancelled claims 10, 11, 15, 16, 19; and amended claim 12, therefore the rejection is moot.

***Claim Rejections - 35 USC § 102***

4. Claims 8-17, 19, 38, 40, 59, 61, 62 were previously rejected under 35 U.S.C. 102(e) as being anticipated by Mazzuca et al. (US. Pub. No. 2005/0070915).

Applicant cancelled claims 7, 9-11, 13-17, 19, 40 and 62; and amended claims 8, 12, 20, 38, 59 to entitle to the PCT filing date, therefore Mazzuca is not a prior art, and the rejection is moot.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 8, 12, 20, 36-39 and 78 rejected under 35 U.S.C. 103(a) as being unpatentable over "Percutaneous Vertebroplasty Guided by a Combination of CT and Fluoroscopy" by Gangi et al. (cited by applicant; hereinafter "Gangi") in view of US 4,250,887 to Dardik et al. (hereinafter "Dardik").

Concerning claims 37 and 78: Gangi discloses a method of delivering a viscous bone cement material under fluoroscopy to a site in a patient (see Technique of Injection section), comprising: providing a delivery device/tube having: a container (i.e. a syringe) containing a viscous bone cement (see page 82, top of the second column)

prior to the bone cement having set, the container having an exit port; locating the container with respect to the patient so that cement leaving the container through the exit port is delivered to a desired injection site within the patient (see Technique of Injection section); and while at least a portion of the patient is subjected to fluoroscopic imaging, driving a flow of viscous bone cement through the exit port to the desired injection site within the patient (see page 84, column 2, I[ 1-3).

Gangi does not specifically discloses an actuator having an actuator vessel, the actuator vessel containing an incompressible fluid; and a hydraulic coupling tube connecting the actuator vessel to the container; and actuating the actuator from a location outside a field of fluoroscopic imaging to hydraulically drive the flow.

Dardik however suggests a method for delivering a viscous material (col. 3, l. 64) under a radiation field 14 and capable of delivering a viscous material, namely bone cement (naturally follows from similar structure to applicant), to a site in a patient comprising the steps of: providing an actuator 22 having an actuator vessel, the actuator vessel containing an incompressible fluid 35; and a hydraulic coupling tube 33 connecting the actuator vessel to a container 25; and actuating the actuator from a location outside a field of radiation to hydraulically drive the flow of the viscous material from the container (Fig. 1 ; col. 2, l. 61 to col. 3, l. 15). Dardik suggests this method in order to reduce the radiation exposure to the surgeon (Abstract).

It would have been obvious to someone of ordinary skill in the art at the time of the invention to add the actuator, hydraulic coupling tube and actuation step of Dardik to the method of Gangi in order to reduce the radiation exposure of the surgeon. The

entire modified device of Gangi, in view of Dardik, can be considered a delivery tube in the sense that applicant's entire device can be considered a delivery tube.

The delivery tube 33 of Dardik is flexible and noncompliant (col. 5, II. 15-20); a linear actuator 22 (Dardik) is involved; determining the amount delivered can be made from a visualization window 20 (Dardik; col. 5, II. 3-7); a separator (26 and 38 of Dardik); cannula (see Technique of Injection of Gangi).

7. Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gangi in view of Dardik as applied to claim 37 above and further in view of US 5,431,654 to Nic (hereinafter "Nic").

Gangi, in view of Dardik, fairly suggests the claimed invention but not specifically force amplification. Nic, however, discloses that during injection of bone cement it may be necessary to amplify the force applied as the bone cement becomes less flowable (col. 10, I. 20-34). It would have been obvious to someone of ordinary skill in the art at the time of the invention to amplify the force in the modified invention of Gangi, in view of Dardik, if the bone cement becomes less flowable. Amplifying force using mechanical advantage was a known method at the time of the invention. Therefore, claim 51 would have been obvious because amplifying force using mechanical advantage was a part of the ordinary capabilities of one skill in the art.

8. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over "Percutaneous Vertebroplasty Guided by a Combination of CT and Fluoroscopy" by Gangi et al. (cited by applicant; hereinafter "Gangi") in view of US 4,250,887 to Dardik et al. (hereinafter "Dardik") and further in view of Haig (US. Pat. No. 4494535).

Gangi, in view of Dardik failed to teach cooling the bone cement to delay its hardening.

Haig teaches cooling the bone cement to delay its hardening (col. 2, lines 18-22).

It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to cool the cement in view of Haig for insuring maximum length of the liquid phase of the cement necessary for its injection.

9. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over "Percutaneous Vertebroplasty Guided by a Combination of CT and Fluoroscopy" by Gangi et al. (cited by applicant; hereinafter "Gangi") in view of US 4,250,887 to Dardik et al. (hereinafter "Dardik") and further in view of Voellmicke et al. (US. Pat. No. 7008433)

Gangi, in view of Dardik failed to teach delivering 10 ml of cement to a bone.

Voellmicke teaches delivering 10 ml of cement to a bone (col. 1, lines 5-14).

It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to deliver up to 10ml of cement in view of Voellmicke for effectively repair a bone fraction and providing an effective fixation system.

***Response to Arguments***

Applicant's arguments with respect to claims have been fully considered but they are not persuasive.

Applicant argues that the system of Dardik will not work with a viscous bone cement. There are three results from constructing the angeographic dye injector in the manner described by Dardick: (1) the surgeon maintains the "feel" of injecting the dye,

even at a distance; (2) the dye is injected at the same rate that the surgeon works the remote plunger; and (3) the device can be made from standard tubing and syringes.

Examiner respectfully disagrees, since Dardik teaches a system for delivering a viscous materials (col. 3; 1. 64), therefore Dardik will work with a viscous bone cement .

Applicant further argues that Gangi does acknowledge the use of fluoroscopic imaging during delivery of bone cement - but Gangi does not specifically addresses the issue of reducing exposure of the surgeon to the X-rays.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Dardik specifically addresses the issue of reducing exposure of the surgeon to the X-rays (abstract).

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMEH BOLES whose telephone number is (571)270-5537. The examiner can normally be reached on Monday - Friday 7:30am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAMEH BOLES/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775